REMARKS

Claims 1-4 and 10-17 will be pending before the Examiner upon entry of the above amendments. Claims 1, 2, 3, and 12 have been amended and claims 5-9 have been canceled. Applicant reserves the right to pursue the subject matter of the canceled claims in a subsequently filed related application. Support for the amendments to the claims may be found in the original claims and the specification at *e.g.*, pages 4-15. Thus, the amended claims are fully supported by the instant specification and no new matter has been introduced.

The specification has been amended to update the priority information and to correct clerical errors as the Examiner suggested. No new matter has been introduced. As such, the objection to the specification has been obviated and should be withdrawn.

According to Applicant's record, the Declaration submitted on November 21, 2001 includes the signature page bearing Applicant's signature, a courtesy copy of the Declaration is enclosed herein.

Although Applicant indicated in the Information Disclosure Statement filed November 11, 2001 that copies of references B1-C19 as listed on the Revised Form PTO 1449 can be found in the parent case of instant application (*i.e.*, USSN 09/520,781), a courtesy copy of each of references B1-C19 is enclosed herein. Applicant respectfully requests that the Examiner considers the cited references.

Non-Statutory Double Patenting

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 14 and 19 of copending and commonly owned Application No. 09/957,187.

Applicant respectfully submits that the instant application (filed November 21, 2001) and copending Application No. 09/957,187 (filed September 19, 2001) were, at the time the invention was made, owned by CuraGen Corporation. Therefore, Applicant submits herewith an appropriately executed Terminal Disclaimer rendering the rejection moot and respectfully requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 112

A. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement, Should Be Withdrawn

The Examiner acknowledges that the specification is enabling for an isolated nucleic acid sequence that encodes a polypeptide of SEQ ID NO:10. See Office Action, first sentence of Paragraph 7. However, the Examiner rejects claims 1-17 under 35 U.S.C. § 112, first paragraph, for failing to reasonably provide enablement for a nucleotide sequence encoding a protein mutant or variant of polypeptide of SEQ ID NO:10, wherein the mutant or variant has no specified activity, or sequences that hybridizes under stringent conditions with no defined conditions, or fragments of the nucleic acid encoding the polypeptide.

Applicant respectfully submits that the claims as amended only recite a nucleic acid sequence encoding a polypeptide of SEQ ID NO:10, or a nucleic acid sequence encoding a polypeptide that has conservative amino acid substitutions to the polypeptide of SEQ ID NO:10 (of which polypeptide has the same function(s) to the polypeptide of SEQ ID NO:10 by definition). As such, the rejection has been obviated and should be withdrawn.

B. Rejections Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner states that (1) the specification fails to teach a skilled artisan how to use the claimed nucleotides to make biologically active SECX (polypeptide of SEQ ID NO:10 and variant thereof) without resorting to undue experimentation to determine what the specific biological activities of the SECX are, because function cannot be predicted based solely on structural similarity; and (2) the claimed nucleic acid sequences that have at least 90% identity to the nucleic acid of SEQ ID NO:9 or a variant thereof fail to recite a specific, measurable activity such that one can recognize a polynucleotide as claimed, or a fragment thereof.

The Examiner is in essence rejecting claims 1-17 for lacking of written description of how to use the claimed nucleic acids. Applicant respectfully submits that the instant specification sufficiently describes how to use the claimed nucleic acids as discussed below.

According to the case law and M.P.E.P., Applicants only need to assert one specific, substantial and credible utility of the claimed invention:

> It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (*e.g.*, a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (*e.g.*, product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility.

M.P.E.P. § 2107.02, I (Eighth Edition, August 2001, revised February 2003).

The instant specification asserts and describes a specific, substantial and credible utility of the claimed nucleic acids for differentiating malignant colon or ovary tissues from corresponding normal tissues. For example, the specification at, *e.g.*, pages 84-85, teaches how to detect the presence or absence of the claimed nucleic acids in a biological sample. Moreover, Example 8 (pages 101-104) and Figure 20 give a working example and clearly shows that a nucleic acid sequence encoding SEQ ID NO:10 is overexpressed in colon cancer cells and ovarian cancer cells as compared to corresponding normal tissues. Therefore, the specification teaches how to use the claimed nucleic acids to differentiate malignant colon or ovary tissues from normal colon or ovary tissues.

In view of the foregoing, Applicant respectfully requests the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

C. Rejections Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner states that (1) claim 1 and its dependent claims are

vague and indefinite because it is unclear whether a fragment of the nucleic acid sequence of (a), (b) or (c) recited in claim 1 would encode the polypeptide of (a); (2) claim 3 and 4 are indefinite because a sequence that is complementary, a mutant or variant to items (a) – (d) of claim 1 may not encode the same protein; and (3) claim 7 and its dependent claims are indefinite because claim 7 does not recite the specific hybridization conditions considered to be "stringent conditions."

Applicant respectfully submits that the claims as amended only recite a nucleic acid sequence encoding a polypeptide of SEQ ID NO:10, or a nucleic acid sequence encoding a polypeptide that has conservative amino acid substitutions to the polypeptide of SEQ ID NO:10 (of which polypeptide has the same function(s) to the polypeptide of SEQ ID NO:10 by definition). Therefore, the rejection has been obviated and should be withdrawn.

Rejection Under 35 U.S.C. § 102 (b)

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Ashkenazi *et al.*, which teaches a nucleic acid sequence that is 92.8% identical to the nucleic acid encoding the polypeptide of SEQ ID NO:10 in the instant application.

Applicant respectfully submits that claim 1 has been amended and it no longer recites a nucleic acid sequence that is 90% identical to the nucleic acid encoding the polypeptide of SEQ ID NO:10. Ashkenazi *et al.* does not teach the claimed sequences of the instant application, and therefore, the rejection under 35 U.S.C. § 102(b) should be withdrawn.

CONCLUSION

Applicant respectfully requests that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Christina K Stock, Reg. No. 45,899

Ivor R. Elrifi, Reg. No. 39,529
Attorney for Applicants
c/o MINTZ LEVIN
Tel.: (617) 542-6000
Fax: (617) 542-2241
Customer No. 30623

Dated: June 29, 2004

Enclosures

TRA 1934275v1

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

COPY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and sole inventor of the subject matter which is claimed and for which a utility patent is sought on the invention entitled:

NOVEL POLYNUCLEOTIDES AND PROTEINS ENCODED THEREBY

the specification of which:

☒ was filed on **March 8, 2000**, as United States non-provisional application **U.S.S.N.** _____, bearing Attorney Docket No. 15966-540 (Cura-40).

☐ is attached hereto.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

☒ I hereby claim the benefit under Title 35, United States Code, § 119(e) or §120 of any United States application(s), or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

Application No. *(U.S.S.N.)*	**Filing Date** *(dd/mm/yy)*	**Status** *(Patented, Pending, Abandoned)*
60/123,667	9 March 1999	Pending

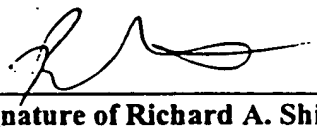
I hereby appoint the following attorneys and/or agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Attorney or Agent	Registration No.	Attorney or Agent	Registration No.
Kevin Ainsworth	39,586	Kristin E. Konzak	44,848
Ingrid Beattie	42,306	Cynthia Kozakiewicz	42,764
David B. Bernstein	32,112	Barry Marenberg	40,715
David F. Crosby	36,400	William Marino	44,219
James G. Cullem	43,569	Leslie Meyer-Leon	37,381
Brett N. Dorny	35,860	A. Jason Mirabito	28,161
Marianne Downing	42,870	Michel Morency	Limited Recognition
Ivor R. Elrifi	39,529	Bradley Olson	40,750
Heidi A. Erlacher	45,409	Carol H. Peters	45,010
Christina Gadiano	37,628	John T. Prince	43,091
John A. Harre	37,345	Michael Renaud	44,299
Shane Hunter	41,858	Brian Rosenbloom	41,276
David E. Johnson	41,874	Thomas M. Sullivan	39,392
Kris Kalidindi	41,461	Howard Susser	33,556
Christina Karnakis	45,899	Shelby J. Walker	45,192
Robert Klauzinski	42,742	Martin M. Zoltick	35,745

Please address all telephone calls to Ivor R. Elrifi at telephone number 617/348-1747. Please address all correspondence to:

Ivor R. Elrifi
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issued thereon.



6/5/00

Signature of Richard A. Shimkets Date

Full Name of Inventor:	Richard A. Shimkets
Citizenship:	United States
Residence:	191 Leete Street, West Haven, CT 06516
Post Office:	same

TRADOCS:1331832.1(SJNC01!.DOC)